REMARKS

Status of the Claims

Claims 10-23, 30-35 and 37-41 are pending.

Claims 10 and 17 are rejected under 35 U.S.C. § 102.

Claim 41 is objected to.

Claims 10-23, 30-35 and 37-41 are rejected under 35 U.S.C. 112.

Amendments

Applicants believe that no new matter has been added to the specification, nor have the amendments broadened the scope of the claims. Basis for the amendments can be found in the claims as originally filed and throughout the instant specification.

Claim Objections

The Examiner has stated that the subject matter of Claim 41 is allowable, but is rejected as being dependent upon a rejected base claim. Applicants believe that the present amendments make the base claim allowable and believe the rejection is now moot.

Section 112 Rejections

Applicants gratefully acknowledge the withdrawal of the previous rejections under 35 U.S.C. 112, first paragraph. However, the Examiner has newly rejected the claims under 35 U.S.C. 112, second paragraph.

First, the Examiner states that claim 15 is indefinite as part of the formula is missing. In response, Applicants have amended the claims to correct this typographical mistake.

Secondly, the Examiner alleges that claims 10-23 are indefinite as the term "including" is open-ended. In response Applicants have amended the claims to substitute the word "or" for "including" thereby defining the metes and bounds of the claim.

Thirdly, the Examiner contends that claims 30-35 and 37-40 are indefinite as the claim language may read on diseases that may not be affected by inosine monophosphate dehydrogenase (IMPDH) antagonists, and because no particular disorder is recited. Applicants respectfully traverse.

On page 70, lines 7 –14 of the instant specification, an IMPDH-associated disorder is defined to be

> any disorder or disease state in which inhibition of the enzyme IMPDH (inosine monophosphate dehydrogenase, EC1.1.1.205, of which there are presently two known isozymes referred to as IMPDH type 1 and IMPDH type 2) would modulate the activity of cells (such as lymphocytes or other cells) and thereby ameliorate or reduce the symptoms or modify the underlying cause(s) of that disorder or disease.

Accordingly, Applicants believe that the claims, which are to be read in light of this definition, adequately exclude diseases that are not affected by IMPDH antagonists and request withdrawal of the rejection under 35 U.S.C. 112, second paragraph.

Secondly, it is known in the art that inhibitors of IMPDH I and II block the proliferation of B and T cells, thereby acting as immunosupressants. Accordingly, it is accepted in the art that inhibitors of IMPDH I and II, are useful in treating a number of disorders characterized by the proliferation of B and T cells. This is discussed in the Specification (page 2, line 34 through page 3, line 13) and reproduced below for the Examiner's convenience.

> United States patents 5,380,879 and 5,444,072 and PCT publications WO 94/01105 and WO 94/12184 describe mycophenolic acid ("MPA") and some of its derivatives as potent, uncompetitive, reversible inhibitors of human IMPDH type I and type II. MPA has been demonstrated to block the response of B and T-cells to mitogen or antigen. Immunosuppressants, such as MPA and derivatives of MPA, are useful drugs in the treatment of transplant rejection and autoimmune disorders, psoriasis, inflammatory diseases, including, rheumatoid arthritis, tumors and for the treatment of allograft rejection. These are described in U.S. Pat. Nos. 4,686,234, 4,725,622, 4,727,069, 4,753,935, 4,786,637, 4,808,592, 4,861,776, 4,868,153, 4,948,793, 4,952,579, 4,959,387, 4,992,467, and 5,247,083.

By virtue of the standard in vitro test described in the Specification (page 96, first and second paragraphs), the compounds of the present invention have been demonstrated to be potent inhibitors of IMPDH I and II, having similar activity to that of MPA and its derivatives. Applicants thus reasonably believe that the compounds of the present invention will be useful in the treatment of all IMPDH-associated disorders (as defined above), not merely a single disorders. Accordingly Applicants respectfully request withdrawal of the indefiniteness rejection under 35 U.S.C. 112, second paragraph.

Section 102 Rejections

The Examiner has rejected claims 10 and 17 under 35 U.S.C. 102(b) as being anticipated by Tanaka et al., Latham et al., and Bradbury et al.

In response, Applicants have amended claim 10 to provide that when R^1 is alkyl, substituted alkyl or alkenyl, R^2 is not cyano. Basis for this amendment is provided in the Examples. Since the compounds of Tanaka et al., Latham et al., and Bradbury et al. all require alkyl, substituted alkyl or alkenyl in the R^1 position and a cyano in the R^2 position. Applicants believe that the currently amended claims are not anticipated by the foregoing art for at least this reason. Since claim 17 is dependent on claim 10, Applicants believe that the amendments render the rejection of claims 10 and 17 under 35 U.S.C. 102 moot.

Applicants believe that each of the Examiner's grounds for rejection is properly stated, traversed, accommodated or rendered moot and that the present application is now in condition for allowance.

FEES

No fees should be due. However, if it is determined that a fee is due, please charge same to Deposit Account No. 19-3880 in the name of Bristol-Myers Squibb Company.

SUMMARY

In view of the foregoing, it is requested that this case proceed to issuance. The Examiner is invited to contact the undersigned if it is believed prosecution could be expedited.

Respectfully submitted,

Bristol-Myers Squibb Company
Patent Department
P.O. Box 4000
Princeton, NJ 08543-4000
609-252-5323

Laurelee A. Duncan
Attorney for Applicants
Reg. No. 44,096

Date: August 6, 2003